K120349
p. 1 of 6

APR - 9 2012

510(k) Summary
(per 21 CFR 807.92)

I. Applicant

Ultrasonix Medical Corporation
130 – 4311 Viking Way
Richmond, B.C.
Canada V6V 2K9

Contact Person: Chas Yu, Quality Assurance Manager
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Date Prepared: February 28, 2011

II. Device Name

Proprietary Name: SonixGPS™ Vascular Access Needle Kit

Classification Name: Vessel dilator for percutaneous catheterization

Product Codes: DRE

Classification Regulation: 21 CFR 870.1310

Classification Panel: Cardiovascular

III. Predicate Device

The SonixGPS™ Vascular Access Needle Kit is substantially equivalent to K081940 – Avalon Elite Vascular Access Kit.

IV. Description of the Device

The SonixGPS™ Vascular Access Needle Kit includes:

Vascular Access Needle:

Disposable sterile vascular access needle

Sensor Introducer:

Disposable sterile sensor introducer into which the needle sensor (K111818) is inserted

Cover:

Disposable sterile cover provides a barrier to prevent transfer of microorganisms, body fluids and' particulate material to the reusable component.

V. Indications for Use of the Device

The device is intended for use by a trained physician in conjunction with the SonixGPS Needle Sensor to assist in vessel cannulation.

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VI. Technological Characteristics

The SonixGPS™ Vascular Access Needle Kit has a similar vascular access needle as the predicate needle in terms of the materials, construction, tip configuration and needle hub. It also provides the same capability to accommodate standard 0.038" size guide wires. The difference in gauge of the SonixGPS™ Vascular Access Needle Kit does not affect function, performance or Intended Use, as compared to predicate device.

The SonixGPS™ Vascular Access Needle is to be used in conjunction with the SonixGPS™ needle sensor (K111818) and theSonixGPS™ ultrasound systems (K093462 and K102997) to provide real-time needle guidance which limits complications and minimizes the number of vessel access attempts.

Table 1 – Technological Similarities and Differences

		SonixGPS Vascular Access Kit	**Avalon Elite Kit**
Main Needle	**Needle - Cannula Material**	Stainless Steel 304 Cannula	same
	Needle - Cannual Diameter	Ga 17	Ga 18
	Needle - Hub	Plastic with Luer lock feature	same
	Needle - Tip	Bevel Tip	same
	Sensor Introducer	Included in Subject kit	Not included in predicate kit
	Cover	Included in Subject kit	Not included in predicate kit
Accessory - Dilator		Not Included in subject Kit	Included in Predicate kit
Accessory - 0.038" Guidewire		Not Included in subject Kit	Included in Predicate kit
Accessory - Scalpel		Not Included in subject Kit	Included in Predicate kit
Accessory - Syringe		Not Included in subject Kit	Included in Predicate kit

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VII. Performance Testing

SonixGPS™ Vascular Access Needle Kit
Underwent the following validation testing:

- Biocompatibility
- LAL Bacterial Endotoxins
- Packaging integrity
- Sterilization validation
- Mechanical

Applicable Standard	Test	Result
ISO 10993-5:2009	Cytotoxicity	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria.
ISO 10993-7:2008	Ethylene Oxide Sterilization Residuals	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria.
ISO 10993-10:2009	Sensitization	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria.
ISO 10993-10:2010	Irritation or intracutaneous reactivity	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria.
ISO 10993-11	Systemic toxicity (acute)	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria.
ASTM F756-08	Hemolysis	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria.
FDA guideline on validation of the limulus amebocyte lysate test as an end-product endotoxin test for human and animal parenteral drugs, biological products, and medical devices (December 1987)	LAL Bacterial Endotoxins Testing	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria.

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Applicable Standard	Test	Result
USP 33:2010 <85>	Bacterial Endotoxins Test	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria.
ISO 11607-1:2006 & ISO 11607-2:2006	Sterile Packaging Validation	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria.
ISO 11135-1:2007	ETO Sterilization Validation	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria.
ISO 7864:1993	Sterile Hydodermic Needles for Single Use	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria of the applicable sections.
ISO 9626:1991	Stainless Steel Needle Tubing for Manufacture of Medical Devices	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria of the applicable sections.
ASTM F1140-07	Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria of the applicable sections.
ASTM F1980-07	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria of the applicable sections.
ASTM F2096-04	Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria of the applicable sections.
ASTM F88-09/F88M-09	Standard Test Method for Seal Strength of Flexible Barrier Materials	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria of the applicable sections.

EN 556-1:2001+AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated ""STERILE"" - Part 1: Requirements for terminally sterilized medical devices	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria of the applicable sections.
AAMI TIR 28:2009	Product adoption and process equivalency for ethylene oxide sterilization	The SonixGPS™ Vascular Access Needle Kit met the acceptance criteria of the applicable sections.
ISO 14971:2007	ISO 14971:2007, Medical devices - Application of risk management to medical devices.	The SonixGPS™ Vascular Access Needle Kit met the standard requirements.

VIII. Performance Testing – Animal

Animal performance testing was conducted to demonstrate that SonixGPS™ Vascular Access Needle Kit, Sonix Ultrasound Scanners (K093462 and K102997) and the SonixGPS™ Needle Sensor (K111818) function together without impairing the vessel cannulation function or raising new concerns of safety/effectiveness.

IX. Conclusion

Ultrasonix Medical Corporation claims the SonixGPS™ Vascular Access Needle Kit to be substantially equivalent to the predicate device K081940 – Avalon Elite Vascular Access Kit, as the SonixGPS™ Vascular Access Needle Kit has equivalent intended uses, manufacturing materials, operating principles, physical, and operational specifications as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR - 9 2012

Ultrasonix Medical Corporation
c/o Ms. Paula Wilkerson
Responsible Third Party Official
Intertek Testing Services
2307 E. Aurora Road, Unit B7
Twinsburg, OH 44087

Re: K120349
Trade/Device Name: SonixGPS™ Vascular Access Needle Kit
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel dilator for percutaneous catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: March 12, 2012
Received: March 14, 2012

Dear Ms. Wilkerson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M.A. Villalobos

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120349
Device Name: SonixGPS™ Vascular Access Needle Kit

Indications For Use:

The device is intended for use by a trained physician in conjunction with the SonixGPS Needle Sensor to assist in vessel cannulation.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M.A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120349